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10/806,961

03/23/2004

Greg Marik

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06/04/2009

Medtronic

Attn: Noreen C. Johnson, IP Legal Department

2600 Sofamor Danek Drive

Memphis, TN 38132

EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

06/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/806,961 | Applicant(s) MARIK ET AL. | |
| | Examiner CHERYL MILLER | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,38 and 40-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,38 and 40-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 35-38 and 40-54 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 38 and 40-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 35 and 45 each recite, **“such that at least the third and fourth surfaces of the center member are *not deformed* by the sliding articulating engagement between the center member and the first and second members”**. Support was not found for the limitation of “non-deformable or non deformed in the applicants specification. Support was found for the center member to be a rigid material, an elastomeric material, or a composite material composed of an elastomer with hardened surfaces. It is noted however that the embodiment in which applicant is referring to (*at least* the third and fourth surfaces) is the composite embodiment and no support was found for the hardened surfaces to be the rigid biocompatible materials *and non-deformable*. A hardened surface may be the same elastomer used for the core, simply cross-linked or a lower water content on the surface (not necessarily the

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“rigid” materials disclosed by applicant, metals, ceramics, etc). Thus the center member having *at least* the third and fourth surfaces of a rigid and non-deformable material is considered new matter. Claims 38, 40-44, and 46-54 depend upon claims 35 and 45 and inherit all problems associated with the claims. Although applicant supports the center member to be an elastomer with harder outer surfaces, support is not provided that the outer surfaces are non-deformable. Non-deformable is not an inherent feature of the harder outer surfaces. If the above quoted recitation were deleted from the claims, the above claims would seemingly be allowable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 55 recites the limitation "the second curve" in line 7. There is insufficient antecedent basis for this limitation in the claim. Claim 56 depends upon claim 55 and inherits all problems with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Kubein-Meesenburg et al. (US 5,336,267). See figures 3 or 5 and respective portions of the specification. Kubein-Meesenburg discloses an implant (capable of placement in a vertebrae) comprising a first member (21 or 41) having a first concave surface (23), a second member (22 or 42) having a second convex projection (24 or 44) having a smaller circular boundary than the first concave surface (see fig.3, 5), and a center member (25) having a third surface (26) and fourth surface (27) and a motion limiting surface (surface extending between 26 and 27 shown to be inclined or tapered), the motion limiting surface spaced from the surface surrounding second convex projection (see fig.3, 5), however when articulated will contact the surface surrounding convex projection (will contact bump seen on right side of 22 in fig.3 or bump on left side of 42 in fig.5). Surface between third and fourth surfaces is shown to be tapered or inclined.

Claim 55 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rogers et al. (US 2004/0002761 A1, cited in IDS). Rogers discloses an intervertebral implant (see fig.21b) comprising a first member (top member of fig.21b) having a first concave recess (bottom concavity), a second member (bottom member of 21b) with a convex projection of a smaller diameter and radius of curvature compared to the first recess (seen in fig.21b), a center member (middle member of fig.21b) having a third convex surface (upper surface) of a smaller diameter and similar curvature to the first radius (this is seen clearly in fig.21b) and a fourth concave surface (bottom concavity of middle member) having a smaller diameter than the second surface and a similar curvature (this is seen clearly in fig.21b),

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and a motion limiting surface (curved rim surface surrounding the concave bottom surface of the center member) that is spaced from the second surrounding surface when aligned (orientation seen in fig.21b) and contacting the surrounding second surface when articulated (not shown, however when center member articulates and tilts with respect to second bottom member, the curved rim will contact the second member limiting further tilting). It appears from Rogers figures 21a, b, and 22a, 22b, that the articulation surfaces are circular. In other figures such as fig.2, 7, and 16 the articulation surfaces are circular so it would seem inherent that they would be also for the embodiment of figures 21 and 22. If not inherent from the figures that the articulation surfaces are each circular, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have circular articulation surfaces, since such would have been a mere obvious change in shape. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Circular peripheries of articulation surfaces are well known in the art of intervertebral prostheses, see other figures of Rogers, for examples figures 2, 7, and 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable under Ferree (US 7,048,764 B2, cited previously). See figure 1B and respective portions of the specification. Ferree discloses an intervertebral implant (see fig.1B; abstract) comprising a first member (top

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member of fig.1b) having a first concave recess, a second member (112) with a convex projection of a smaller diameter and radius of curvature compared to the first recess, a center member (114) having a third convex surface of a smaller diameter (shown to be smaller in fig.1b) and similar curvature to the first radius and a fourth concave surface (bottom concavity of 114) having a smaller diameter than the second surface and a similar curvature (see fig.1b), and a motion limiting surface (bottom flat surface of 114, that surrounds concavity) that is spaced from the second surrounding surface when aligned (orientation seen in fig.1b) and contacting the surrounding second surface when articulated (not shown, however when center member 114 articulates and tilts with respect to second member 112, the flat will contact the second member limiting further tilting). Ferree discloses the intervertebral prosthesis substantially as claimed, however has not disclosed a circular periphery of the articulating surfaces (no shape is disclosed and since no plan top views are provided in the figures, it is unclear what shape the peripheries are). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the articulation surfaces with circular peripheries since such would be a mere change in shape. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Circular peripheries are well known in the intervertebral art, see as evidence Buttner-Janz (US 5,556,431).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738